

DISCUSSION OF THE AMENDMENT

Due to the length of the specification herein, Applicants will cite to the paragraph number of the published patent application (PG Pub) of the present application, i.e., US 2007/0123590, when discussing the application description, both in this section and in the Remarks section, *infra*, rather than to page and line of the specification as filed.

Claim 1 has been amended by adding antecedent basis where appropriate; by deleting the term “beater” and inserting the term --regenerating-- between “aqueous” and “solution” in step a; by replacing the term “comprised between” with appropriate terminology; by reciting that the percentage range in step a refers to the theoretical percentage required for complete regeneration of the resin, as supported in the specification at paragraph [0023] combined with paragraph [0029]; and by deleting the term “itself.”

Claim 3 has been amended by replacing the term “chosen among” with appropriate Markush terminology, or are otherwise clerical in nature.

Claim 19 has been amended to depend on Claim 4.

The remaining amendments have been made to be consistent with the above-discussed amendments to Claims 1 and 3.

No new matter is believed to have been added by the above amendment. Claims 1-24 remain pending in the application.

REMARKS

The rejection of Claims 1-24 under 35 U.S.C. § 103(a) as unpatentable over US 2004/0068011 (Cannata et al), in view of “Ion Exchange” in Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, pp. 1-50 (2000) (Kirk-Othmer), is respectfully traversed.

Cannata et al is from the same patent family as WO 02/34709, described in the specification herein at paragraph [0005] and following. The present invention is described as an improvement over Cannata et al. Particularly, in the regeneration process of Cannata et al, a relatively large quantity of eluants is used, which produces a considerable quantity of so-called scraps, as described in paragraphs [0011]-[0015]. By the process of the present invention, the quantity of scraps can be considerably reduced while at the same time providing a pure product as well and with substantially identical yields, as described at paragraph [0017]. In the presently-claimed process, as recited in step a of Claims 1 and 13, only partial regeneration is carried out at first, using an aqueous inorganic acid solution in a quantity equal to a percentage of resin moles of from only 50 to 90% of the theoretical percentage required for complete regeneration of the resin, followed by adding demineralized water in a quantity sufficient to separate the regenerating solution from a solution of a gabapentin salt, which is the subject of the next step; which step involves adding a solution of gabapentin salt to complete the resin regeneration through the acid released by fixing the gabapentin salt to the resin. As described in the specification herein at paragraph [0023], generally, the acid/resin molar ratios are equal to or a fair excess with respect to the theoretical 1:1 ratio, such as 2.6:1 or 1.5:1. As discussed above, the presently-claimed process involves an initial partial regeneration with a corresponding ratio of (.5-.9):1.

Cannata et al was cited in the International Search Report for the corresponding international application as an “A” reference, i.e., document defining the general state of the

art which is not considered to be of particular relevance. The Examiner relies on Kirk-Othmer for a disclosure of regenerating cation exchangers with mineral acids such as sulfuric acid and hydrochloric acid, and rinsing with water.

In reply, and as discussed above, the presently-claimed invention is not simply regenerating with an acid followed by rinsing with water, but a specific series of steps beginning with only partial regeneration, after which complete resin regeneration is achieved through the acid released by fixing the gabapentin salt to the resin. Such a process is neither disclosed nor suggested by Cannata et al nor Kirk-Othmer, let alone a combination thereof.

For all the above reasons, it is respectfully requested that the rejection be withdrawn.

The rejection of Claims 1-24 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. The rejection would now appear to be moot in view of the above-discussed amendment, except for the Examiner's finding that it is unclear if step b comes before step c.

In reply, step b indeed comes before step c. Step b simply requires that sufficient demineralized water be added so that the solution of gabapentin salt of subsequent step c can be successfully separated from the "beater", i.e., regenerating solution. Accordingly, it is respectfully requested that the rejection be withdrawn.

The provisional rejection of Claims 1-24 on the ground of nonstatutory obviousness-type double patenting over Claims 1-29 of copending Application No. 11/390,451 (copending application), is respectfully traversed.<sup>1</sup> The claims of the copending application are drawn to a process for the purification of gabapentin hydrochloride from inorganic salt impurities and for conversion of the gabapentin hydrochloride into gabapentin, comprising contacting an aqueous gabapentin hydrochloride solution comprising a mixture of gabapentin, gabapentin hydrochloride and inorganic salts with a strong cationic resin which resin retains gabapentin thereon in cationic form, washing the adsorbed gabapentin/ion exchange material with water

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<sup>1</sup> Applicants note that the Examiner refers to Claims 1-29 of the copending application twice in the provisional rejection. Applicants assume that the repetition is superfluous, and that only one application was intended.

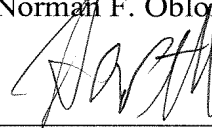
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to remove salt impurities therefrom; and separating and obtaining gabapentin freed of salts from the ion exchange material. The claims of the copending application neither disclose nor otherwise suggest the presently-recited regenerating process, discussed in detail above with regard to the prior art rejection, which discussion is herein incorporated by reference. Accordingly, it is respectfully requested that the provisional rejection be withdrawn.

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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